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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10305]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Part C and Part D Data Validation (42 CFR 422.516g and 423.514g); Use: The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR 422.516(a) and 423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data (depending

on the type of contracts they have in place with CMS).

In order for the reported data to be useful for monitoring and performance measurement, it must be reliable, valid, complete, and comparable among sponsoring organizations. In 2009, CMS developed the data validation program as a mechanism to verify the data reported are accurate, valid, and reliable. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. Instead, sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials.

CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating the sponsoring organizations' data. These standards and criteria are described in Appendix 1 "Data Validation Standards." The data validation standards for each reporting section include standard instructions relating to the types of information that should be reviewed, and reporting section criteria (MSC) that are aligned with the "Medicare Part C and Part D Reporting Requirement Technical Specifications." Furthermore, the standards and criteria describe how the DVCs should validate the sponsoring organizations' compilations of reported data, taking into account appropriate data exclusions, and verifying calculations, source code, and algorithms. The data validation reviews are conducted at the contract level given that the Medicare Part C and Part D data are generally available at the contract level and the contract is the basis of any legal and accountability issues concerning the rendering of services.

The review is conducted over a three-month period following the final submission of data by the sponsoring organizations. In addition to the "Data Validation Standards" described in

Appendix 1, the DVCs employ a set of information collection tools when performing their reviews, which are included in the appendices described below:

Appendix 2: “Organizational Assessment Instrument”

Appendix 3: “Data Extraction and Sampling Instructions”

Appendix 4: “Instructions for the Findings Data Collection Form”

Appendix 5: “Findings Data Collection Form (FDCF)”

Data collected via “Medicare Part C and Part D Reporting Requirements Technical Specifications” is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare benefits to beneficiaries. CMS uses the data collected through the Medicare Data Validation Program to substantiate the data collected via “Medicare Part C and Part D Reporting Requirements Technical Specifications.” If CMS detects data anomalies, the CMS division with primary responsibility for the applicable reporting requirement assists with determining a resolution.

The hour burden on industry is estimated at 179,301 total hours, or 879 hours for one contract within one organization reporting both Part C and Part D reporting sections. The validation would require 378 hours from the sponsoring organization and 501 from the DVCs. The estimates are based on the total number of Part C and/or Part D reporting sections, the average number of sponsors, and the average number of contracts by type (Part C, Part D, Part C/D) being validated as well as a level of effort associated with the individual activities associated with the data validation process. Form Number: CMS-10305 (OMB#: 0938-1115); Frequency: Reporting – Annually; Affected Public: sponsoring organizations. Number of Respondents: 135; Total Annual Responses: 657; Total Annual Hours: 179,301. (For policy

questions regarding this collection contact Terry Lied at 410-786-8973. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on **[Insert date 30 days after date of publication in the Federal Register.]**

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: OIRA_submission@omb.eop.gov.

Dated: November 29, 2012

Martique Jones

Director, Regulations Development Group, Division B

Office of Strategic Operations and Regulatory Affairs

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